

REMARKS

This is a response to the Office Action mailed October 19, 2004. Claims 32-64 are pending in the application. Claims 32-63 have been rejected by the Examiner. As noted above, Applicants have amended Claims 32-34, 37-41, 43, 50 and 57 and submitted New Claim 64. The amendments and the new claim are fully supported by the written description. Also, no new matter has been introduced into the application.

Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected Claims 32-34, 36-41 and 43-63 under 35 U.S.C. §102(e) as being anticipated by Wang (U.S. Patent Number 6,379,379).

A. Claims 32-34, 36-41, 43 and 57

Wang is directed to a stent that “may include a coating or coatings on one or both end portions to provide a smooth finish to reduce possible damage to body passages when the stent is deployed and delivered.” *See* Abstract. Wang does not disclose all of the limitations of amended independent Claims 32, 38 and 57. Although the stent of Wang can include at least one sleeve 46 which is “designed and configured to fit over the end of a stent,” column 8, lines 21-22, there is nothing in Wang that discloses a **strip on a stent body**. The sleeve of Wang, instead, is disposed along the entire circumference of the stent body as clearly shown in Figure 11. This configuration is different from the claimed “strip,” for example, as shown by comparing Figure 11 of Wang with Figure 3 of the present invention.

Because Wang fails to disclose all of the limitations of Claims 32, 38 and 57, these claims should be allowable over Wang. Corresponding dependent Claims 33, 34, 36, 37 and 39-41 should be allowable for at least the same reason.

B. Claims 44-56, 58-60, 62 and 63

The Examiner has proffered an anticipation-by-inherency argument by asserting that “the materials as disclosed by Wang inherently have the creep compliance as claimed.” Applicants,

however, disagree and submit that the Examiner has failed to establish a *prima facie* case for anticipation by inherency.

According to the Federal Circuit, “[u]nder the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element ‘is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *Rosco, Inc. v Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002) (quoting *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)) (emphasis added). In other words, “[i]nherent anticipation requires that the missing descriptive material is ‘necessarily present,’ **not merely probably or possibly present**, in the prior art.” *Id.* (quoting *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002)) (emphasis added).

In moving forward with an inherency rejection, “the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the examiner.” *Ex parte Levy*, No. 90-1864, 1990 Pat. App. LEXIS 18, at *8 (citing *In re Piasecki*, 745 F.2d 1468 (Fed. Cir. 1984)). Moreover, “[i]n relying upon the theory of inherency, **the examiner must provide a basis in fact and/or technical reasoning** to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.” *Id.* at *8-*9 (citing *In re King*, 801 F.2d 1324 (Fed. Cir. 1986)) (emphasis added).

With respect to Claims 44-55 and 58-62, **the Examiner has provided absolutely no basis in fact and/or technical reasoning** why Wang discloses the specific range of creep compliance of about 0.5 GPa⁻¹ to about 10 GPa⁻¹. Instead, the Examiner merely asserts that “the materials of Wang inherently have the creep compliance as claimed.” This bald assertion clearly does not meet the Examiner’s initial burden. See *Ex parte Levy*, 1990 Pat. App. LEXIS 18, at *9-*10 (finding that a prior art reference did not disclose any particular tensile strength of the catheter balloon and therefore there was not a sufficient factual basis or cogent scientific

reasoning to support the conclusion that the prior art reference inherently disclosed the relevant limitations). Because the Examiner has failed to meet her initial burden, the rejection should be removed and the claims allowed.

Furthermore, it is abundantly clear that the materials in Wang would not **necessarily** have the specific creep compliance claimed by the Applicants. The specific creep compliance can be important because it allows the material applied to the stent body to “exert a gradual and weak restoring force that avoids collapsing or substantially deforming an expanded stent over time.” Specification at page 7. There is nothing in Wang that suggests the sleeves would have this particular physical characteristic. Instead, with regard to mechanical properties, Wang merely discloses two concepts. First, Wang discloses that a metal stent body could include materials having different flexibility along the length of the stent. Column 9, lines 39-41. Second, Wang discloses that a sleeve could be made of an elastic material “so that it will stay in place on the stent end portion.” Column 8, line 59-61. Clearly, this second point does not conform to the purpose and scope of the present invention--namely, providing a material on the body of the stent that does not exert an immediate and strong restoring force after being stretched during stent deployment.¹

Finally, although the Examiner might be suggesting that one of the infinite number of polymer materials disclosed in Wang **might** have a creep compliance within the claimed range, such conjecture is insufficient for a finding of inherency. As dictated by the courts, inherency “**may not be established by probabilities or possibilities**. The mere fact that a certain thing **may** result from a given set of circumstances is not sufficient.” *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (*quoting Hansgirk v. Kemmer*, 102 F.2d 212 (CCPA 1939)) (emphasis added).

¹ See, e.g., *In re Oelrich*, 666 F.2d 578, 581-82 (CCPA 1981) (finding that a limitation was not inherently disclosed because, “[t]he Oelrich patent instructs that the device is ‘adapted to receive a carrier frequency substantially in excess of the particular system critical or resonant frequency’ Given this express teaching, a ‘means for generating a . . . carrier frequency . . . less than the minimum system resonant frequency’ is not inevitably present”) (emphasis added).

See also In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (reversed the Board's finding of inherency because it did not cite extrinsic evidence and its "analysis rests upon the very kind of probability or possibility . . . that this court has pointed out is insufficient to establish inherency.")

Moreover, the Examiner has also specifically failed to assert a *prima facie* case against Claims 46, 49, 51, 56, 60 and 63 because the Examiner has remained completely silent on the basis for rejection of these claims. In particular, the Examiner has provided no explanation on why the Wang reference anticipates the limitations directed to the relative physical characteristics of the stent body compared to the material applied to the stent body. For instance, Claim 56 claims "**an expandable structural frame made from a first material having a first modulus of elasticity; and an annular band disposed on a region of the expandable structural frame, the band made from a second material having a second modulus of elasticity, the second modulus of elasticity being lower than the first modulus of elasticity.**"

There is nothing in the Wang reference that explicitly or implicitly suggests that the materials of the stent and sleeve should have these particular relative physical characteristics. As noted above, Wang provides very little guidance on the suggested physical characteristics of the various materials of the stent and sleeves, and certainly does not disclose anything about the modulus of elasticity of any of the components.²

In short, the Examiner's finding of inherency is fundamentally flawed and should be removed. The Wang reference does not disclose the claimed limitations explicitly, implicitly or inherently, and therefore the Examiner's reliance on this reference goes completely against the fundamental principals of patent law. Accordingly, the rejection should be removed and the claims allowed.

² See, e.g., *In re Rijckaert*, 9 F.3d at 1534 (finding that an inherency rejection was improper because "[t]he relationship between the time expansion/compression and the three variables recited in the claims from which claim 6 depends, which is absent in the combination of Awamoto and Driessen, is not supplied by Ohta.")

Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected Claims 35, 42 and 61 under 35 U.S.C. §103 as being as being unpatentable over Wang. As noted above, amended Claims 32 and 38 are allowable over Wang. Claims 35 and 42 depend from Claims 32 and 38, respectively. Accordingly, Claims 35 and 42 are allowable. Furthermore, Claim 58 is allowable over Wang. Claim 61 depends from Claim 58 and should also be allowable.

CONCLUSION

Claims 32-64 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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Respectfully submitted,



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